POLICIES AND PROCEDURES FOR EPIDEMIOLOGICAL STUDIES WITH CO-INVESTIGATORS, USING INDIVIDUAL RECORDS IN THE PATIENT ABSTRACT SYSTEM

THE PATIENT ABSTRACT SYSTEM

The Missouri Department of Health and Senior Services (DHSS), Bureau of Health Informatics (BHI) receives information abstracted from patient medical records of hospitalizations, emergency room visits, outpatient surgery, and selected outpatient services and procedures (CAT scan, MRI, endoscopy, lithotripsy, etc.). Inpatient records of Missouri residents hospitalized in several neighboring states are also included. The patient abstract data are reported to the department each calendar quarter by hospitals and ambulatory surgery centers. The information is held in a secure and confidential data file known as the Patient Abstract System (PAS).

The BHI utilizes PAS information for epidemiologic studies and for surveillance. Other DHSS units and "public health authorities" are also authorized to use PAS records for these purposes.

Researchers who are not members of a public health authority, and organizations external to the DHSS, who are engaged in epidemiologic study of the health status and health care needs of Missouri citizens, may request access to record level PAS information. These researchers must apply to the DHSS to become "co-investigators" with the department. They must promise to protect the confidentiality and the privacy of PAS records. Research proposals are reviewed by an independent Data Release Advisory Committee (DRAC) and submitted to the DHSS Institutional Review Board (IRB) for review, prior to final study approval and release of PAS data. Listed below is the contact for information regarding the Department's IRB policies and procedures:

IRB Chair
Missouri Department of Health and Senior Services
Office of General Counsel
912 Wildwood, P.O. Box 570
Jefferson City, MO 65102-0570
Phone: (573) 751-6005
Email: Info@dhss.mo.gov

DATA RELEASE ADVISORY COMMITTEE (DRAC)

The DRAC is comprised of persons appointed under the authority of the DHSS Director. Represented on the committee are researchers, consumers and health care providers. DRAC members serve as volunteers and receive no compensation.

APPLICABLE STATE LAW AND REGULATIONS

The Missouri state statute (RSMO 192.067) and state regulations (19 CSR 10-33.010) regarding release of PAS information to co-investigators, can be found at the following locations on the Missouri State Government website:

Statute: http://www.moga.mo.gov/statutes/c100-199/1920000067.htm

Regulation: http://www.sos.mo.gov/adrules/csr/current/19csr/19c10-33.pdf

Only public health authorities and DHSS approved co-investigators can receive record level PAS data. Co-investigators are provided access only to information needed to address their specific research questions. They are prohibited from disclosing any information that would identify a patient, physician or provider. Only public health authorities are permitted to contact a patient, physician or provider based on the information supplied in the PAS data, with appropriate authorization by the Department. Any contact with a patient requires that the physician and facility that provided care to the patient also be informed of any proposed contact with the patient. Co-investigators are **not** permitted to contact patients, physicians or providers (facilities) identified in the PAS records provided to them for epidemiological purposes. Co-investigators can only be authorized to conduct statistical analysis of existing data.

APPLICATION AND APPROVAL PROCESS

Persons or organizations desiring to become co-investigators must submit an application on the forms provided by the DHSS. (See Letter to Applicant) Upon receipt of that application, the DHSS staff will conduct an initial screening and review. An application will be immediately rejected if it is determined that 1) it does not clearly describe a well-designed epidemiologic study, 2) the investigator does not have the appropriate expertise, 3) being a co-investigator would overburden the department, or 4) there is reason to believe that confidentiality of the data would be jeopardized by its release. **It is the principal investigator's responsibility to design a valid study that would make a contribution to public health, and it is not the department's role to help refine a faulty study or a poorly described study until it meets generally acceptable scientific standards.** Protocols of this nature will be rejected. Further processing of such applications will be discontinued, due to the amount of staff time that would be consumed by ongoing review and revision.

A valid epidemiological study requires a clear statement of the purpose and hypotheses, as well as a description of the hypotheses and study methods in terms of the data items being requested. Therefore, it is recommended that researchers interested in obtaining DHSS data should first obtain documentation for the requested data sets and become familiar with the data sets prior to designing their studies. This will make it more likely that the study will pass review and ensure that the investigator requests exactly the data items needed for the study. General descriptions do not allow accurate assessment of the value of the study or the need for the data items, and may result in rejection of the study proposal.

DHSS staff will conduct the first review of the application and research protocol. The DHSS in-house review will follow the same review criteria expected of the DRAC. All applications for co-investigative study will also require approval by the DHSS Office of the Director and review by the DHSS IRB.

The DHSS will mail copies of the application and research protocol to each member of the DRAC for review, comment and recommendation. Whenever a committee member has questions concerning the application or protocol, the DHSS will submit those questions to the principal investigator. If any reviewer expresses doubt and plausible reason for concern about the proposed study, especially with regard to confidentiality and data security, the principal investigator will have the burden of providing satisfactory assurances to both the DHSS and the committee that no unacceptable risk exists.

PROVIDING DATA TO THE COINVESTIGATOR

During the review period, staff of the BHI will examine the application and determine which PAS data elements are necessary for the analysis proposed in the research protocol. The principal investigator will be notified of any discrepancy between the list of data elements requested in the research proposal and those determined by DHSS staff to be needed. Only those data elements deemed necessary for the proper conduct of the approved research will be provided to the co-investigator. Some data processing summations and/or statistical analysis may be performed by the DHSS staff, in cooperation with the co-investigator.

The data are released to the co-investigator for a **single approved study**. The co-investigator shall not release data records to anyone not involved in conducting the study. The co-investigator **must** destroy all copies of the data after all analyses for the specific approved study have been concluded.

MONITORING, FOLLOW-UP AND OVERSIGHT

Progress reports will be requested from the principal investigator on an annual basis (or more frequently, if deemed necessary).

Requests for extension of time to complete the project must be submitted to the DHSS in writing. If review and oversight has not identified any matters of concern, the first request for time extension, if reasonable, will be approved. Subsequent requests for time extensions must be adequately justified.

All changes to the research protocol require approval by the DHSS in advance.

All changes in research staff must be immediately reported to the DHSS.

On-site inspections by DHSS staff may occur at the discretion of the Department.

REPORTING RESULTS AND FINDINGS

All preliminary and final reports, publications and/or public presentations regarding the study and study results shall be prepared jointly with the DHSS or submitted to the Department for prior approval. The DHSS may revise such reports, publications and presentations so that they are acceptable to both the Department and the co-investigator. The DHSS may submit to the co-investigator written material to be included in any report, publication or presentation if the Department believes these changes or additions improve the accuracy, completeness or quality of the report, publication or presentation.

CANCELLING THE PROJECT BEFORE COMPLETION

If the DHSS receives any credible report or evidence that unauthorized release of data or other breach of confidentiality may have occurred, the Department will **immediately** suspend the research project and investigate whether such unauthorized release or other breach has, in fact, happened.

If the DHSS determines that, by either willful intent or negligence,

- data has been released to unauthorized persons
- the identity of a patient, physician, or provider has been revealed to a person not listed as research staff on the approved research protocol, or
- data is being used in an unapproved manner,

the Department will withdraw as a co-investigator from the study and order that all PAS data and other information provided to the principal investigator by the Missouri DHSS be destroyed.

RELATED INFORMATION AND FORMS

Letter to Applicant

Confidentiality Agreement

Agreement for Oversight

DHSS IRB

Data Fee Policy

Policy and Procedures for Release of Vital Records Information